UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

JANET ROLWES,	)	
Plaintiff,	)	Cause No.: 4:03CV00151CAS
vs.	)	
CENTOCOR, INC., and JOHNSON & JOHNSON,	)	
Defendants.	)	

DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT

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PRELIMINARY STATEMENT

This is a products liability action in which Janet Rolwes seeks damages for injuries allegedly caused as a result of her use of Remicade®. According to Ms. Rolwes, defendants Centocor, Inc. and Johnson & Johnson (collectively, "Centocor") are liable for allegedly failing to warn Ms. Rolwes' physician, Dr. Robert Uchiyama, of the medicine's risks.

Pursuant to the Court's October 8, 2003, Case Management Order, Centocor now moves for summary judgment because the incontrovertible material facts demonstrate that (1) Ms. Rolwes cannot establish that Remicade® was a cause-in-fact of her injuries, (2) Centocor adequately warned Ms. Rolwes' prescribing physician of the potential risks associated with Remicade®, and (3) the warnings provided by Centocor were not a proximate cause of any injury to Ms. Rolwes. In addition, Johnson & Johnson – Centocor's parent company with no direct involvement with Remicade® – also is entitled to summary judgment.

STATEMENT OF FACTS

For purposes of this motion, Centocor submits the following facts are undisputed:

Ms. Rolwes' Condition Before Remicade®

Ms. Rolwes first tested positive for tuberculosis when she was a teenager in the 1960s. (Defs.' Statement of Uncontroverted Material Facts Pursuant to Local Civil Rule 7-4.01(E) (hereinafter "Uncontroverted Facts") ¶ 1.) She did not have symptoms of active tuberculosis, but had latent tuberculosis. (Id.) When she began teaching at the Francis Howell School District in 1987, she was required to have a tuberculosis test and the first skin test Ms. Rolwes took as a teacher was positive. (Id. ¶¶ 2, 3.) Thereafter, Ms. Rolwes' latent tuberculosis was monitored by way of chest x-rays. (Id. ¶ 3.)

In the early 1980s, Ms. Rolwes was diagnosed with rheumatoid arthritis. (Id. ¶ 4.) Rheumatoid arthritis is an autoimmune disease that can be serious and rapidly debilitating. It

involves the chronic inflammation and destruction of joints and can result in suppression of the patient's immune system. (Id. ¶¶ 5, 14.)

Dr. Uchiyama treated Ms. Rolwes' "fairly severe" rheumatoid arthritis from October 1996 through February 2002. (Id. ¶¶ 6, 8.) Because of her history of positive skin tests, Ms. Rolwes was at an increased risk of developing active tuberculosis. Dr. Uchiyama examined Ms. Rolwes regularly and sent her for periodic chest x-rays. (Id. ¶¶ 1, 16.) Dr. Uchiyama also continued Ms. Rolwes on medications previously prescribed for the treatment of her rheumatoid arthritis – methotrexate and prednisone, a corticosteroid. (Id. ¶ 9.) Both methotrexate and prednisone are immunocompromising medicines and are specifically associated with a risk of tuberculosis, which risk increases the longer a patient takes the medications. (Id. ¶¶ 56-57, 59-60.)

Despite the medications Ms. Rolwes was taking, her rheumatoid arthritis became progressively worse and, by January 2000, it had reached to the point where her joints were irreversibly damaged. (Id. ¶ 17.) At that point, Ms. Rolwes also had numerous painful nodules on her hands that inhibited her ability to function. (Id. ¶ 40.)

Ms. Rolwes' Condition After Remicade®

Ms. Rolwes first discussed Remicade® with Dr. Uchiyama in January 2000 and began receiving Remicade® infusions in May 2000. (Id. ¶¶ 22, 33.) Prior to starting Remicade® therapy, Ms. Rolwes was warned:

> WARNINGS
>
> Risk of Infections
>
> Serious infections, including sepsis and fatal infections, have been reported in patients receiving TNF-blocking agents. Many of the serious infections in patients treated with Remicade® have occurred in patients on concomitant immunosuppressive therapy that, in addition to their Crohn's disease or rheumatoid arthritis, could predispose them to infections. Caution should be exercised

> when considering the use of Remicade® in patients with a chronic infection or a history of recurrent infection. Remicade® should not be given to patients with a clinically important, active infection. Patients who develop a new infection while undergoing treatment with Remicade® should be monitored closely. If a patient develops a serious infection or sepsis, Remicade® therapy should be discontinued (see ADVERSE REACTIONS, Infections).
>
> • • •
>
> ADVERSE REACTIONS
>
> Infections
>
> In the ATTRACT study, one patient died with disseminated tuberculosis and one died with disseminated coccidioidomycosis. The relationship to REMICADE® is unknown (see WARNINGS, Risk of Infections).

(Id. ¶ 29.) Although she could not specifically recall reading this warning when she was deposed, Ms. Rolwes described this warning as a "red flag." (Id. ¶ 30.) In addition, while receiving Remicade® Ms. Rolwes reviewed other materials describing the medicine's risks.

After beginning Remicade® treatments, the painful nodules on Ms. Rolwes' hands disappeared. (Id. ¶ 41.) Moreover, Ms. Rolwes began to feel better, her rheumatoid arthritis symptoms improved, and she was better able to cope with her disease. (Id. ¶¶ 41-44.)

Within her first four months of Remicade® therapy, Ms. Rolwes had a chest x-ray that was negative, showing no signs of active tuberculosis. (Id. ¶ 38.) From May 2000 through October 2001, while Ms. Rolwes was receiving Remicade® treatments, she did not report any side effects. (Id. ¶ 39.) Nor was there any indication that Ms. Rolwes' latent tuberculosis had reactivated. (Id. ¶ 47.) Then, in mid-November 2001, Ms. Rolwes developed symptoms of active tuberculosis. (Id. ¶ 48.) The diagnosis of active tuberculosis was confirmed in January 2002, and it fit neither the temporal relationship for onset (within seven months of first infusion) nor the type (disseminated or extrapulmonary tuberculosis) that had been seen with other Remicade® patients. (Id. ¶¶ 49, 63.)

Ms. Rolwes' tuberculosis was cured by June 2002. (Id. ¶ 51.) Moreover, her chest x-rays today are virtually indistinguishable from those taken in August 2000 in that no significant tuberculosis scarring is evident. (Id. ¶ 52.)

Dr. Uchiyama's Knowledge of Remicade®

At the time he prescribed Remicade® to Ms. Rolwes, Dr. Uchiyama was fully aware that it was an immunocompromising medicine that could increase a patient's risk of infections, including tuberculosis. (Id. ¶ 35.) In fact, between December 1999 and October 2001, Centocor sent information discussing the risk of infection to Dr. Uchiyama six times, either as part of general mailings to Remicade® prescribers or in response to specific inquiries by Dr. Uchiyama. (Id. ¶ 67.) Dr. Uchiyama was familiar with and understood the indications, contraindications, warnings, precautions, and adverse events associated with Remicade® as described in the medicine's prescribing information. (Id. ¶ 23-25, 29.) In addition, he relied on his independent knowledge and experience as a rheumatologist in prescribing Remicade® to Ms. Rolwes. (Id. ¶¶ 13-15, 35.)

When Dr. Uchiyama first discussed Remicade® with Ms. Rolwes in January 2000, Centocor was aware of only two reports of tuberculosis among the almost 200,000 people who had received the medicine. Between January and October 2000, additional information became available to FDA and Centocor regarding tuberculosis and Remicade® therapy. (Id. ¶¶ 69, 70.) Although this data was inconclusive, Centocor proposed additional language to incorporate into the Remicade® prescribing information, which FDA approved in December 2000:

> Serious infections, including sepsis and disseminated tuberculosis, have been reported in patients receiving TNF-blocking agents, including Remicade®. Some of these infections have been fatal. . . . . Caution should be exercised when considering the use of Remicade® in patients with a chronic infection or a history of recurrent infection. Remicade® should not be given to patients with a clinically important, active infection. Patients should be monitored for signs and symptoms of infection while on or after

> treatment with Remicade®. New infections should be closely monitored. . . . Patients should be evaluated for the risk of tuberculosis, including latent tuberculosis. Treatment for tuberculosis should be initiated prior to treatment with Remicade®.

(Id. ¶ 71.) This information was sent to Dr. Uchiyama two times in 2001 (id. ¶¶ 67, 72), and Ms. Rolwes' expert describes this warning as "very helpful." (Id. ¶ 76.)

ARGUMENT

THE LEGAL STANDARD GOVERNING CENTOCOR'S MOTION FOR SUMMARY JUDGMENT

The Court should grant Centocor's motion for summary judgment if the record shows "that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c) (2003); see also McCown v. St. John's Health Sys., Inc., 349 F.3d 540, 542 (8th Cir. 2003). The moving party must demonstrate the absence of a genuine issue of fact, such that a reasonable jury could not return a verdict for the non-moving party. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986); Hartford Underwriter's Ins. Co. v. Estate of Turks, 206 F. Supp. 2d 968, 970 (E.D. Mo. 2002). The burden then shifts to the non-moving party, who can defeat a summary judgment motion by providing affirmative evidence and setting forth specific facts demonstrating that a genuine issue of triable fact exists. See Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986); Uhiren v. Bristol-Myers Squibb Co., 346 F.3d 824, 827-28 (8th Cir. 2003). Here Centocor has clearly satisfied its summary judgment burden.

Self-serving, conclusory statements, like the ones made by Ms. Rolwes' expert, are insufficient to defeat summary judgment. See Council of Better Bus. Bureaus, Inc. v. Bailey & Assocs., Inc., 197 F. Supp. 2d 1197, 1202 (E.D. Mo. 2002) (citing Armour and Co. v. Inver Grove Heights, 2 F.3d 276, 279 (8th Cir.1993)). Ms. Rolwes must provide more than "a scintilla of evidence," Anderson, 477 U.S. at 252, and "do more than simply show that there is some

metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986).

Summary judgment is warranted here because Ms. Rolwes cannot provide specific evidence to demonstrate that a triable issue of fact exists. First, Ms. Rolwes cannot show that her use of Remicade® was an actual or proximate cause of any injury to her. Second, Ms. Rolwes' prescribing physician, Dr. Uchiyama, was fully and independently aware of the potential risks associated with Remicade®. Thus, Centocor satisfied its duty to inform the learned intermediary with FDA-approved warnings and the uninformed, unsubstantiated "say so" of Ms. Rolwes' expert is not enough to order a trial here.

POINT I

MS. ROLWES CANNOT ESTABLISH THAT REMICADE® ACTUALLY CAUSED ANY INJURY

A. Standard for Actual Causation

To establish liability under a negligence or products liability cause of action, a plaintiff must demonstrate actual causation by showing that her injuries resulted from the defendant's product. Nelson v. Am. Home Prods. Corp., 92 F. Supp. 2d 954, 957 (W.D. Mo. 2000) (applying Missouri law). "Evidence of causation must be based on probative facts, not on mere speculation or conjecture." Kircher v. Purina Mills, Inc., 775 S.W.2d 115, 117 (Mo. 1989). A submissible case on causation is established when the evidence is "susceptible to a reasonable inference" that plaintiff's injuries resulted from the defendant's product, thereby demonstrating that the injury or damage was not the result of several equally probable causes. Id.; see also Tenbarge v. Ames Taping Tool Sys., Inc., 128 F.3d 656, 659 (8th Cir. 1997).

B. Failure to Show Causation

Ms. Rolwes cannot demonstrate that her reactivated tuberculosis probably resulted from her use of Remicade® because she has no expert proof, based on scientific

principles, demonstrating that Remicade® more likely than not caused her active tuberculosis infection in late 2001. See Nelson, 92 F. Supp. 2d at 957. Ms. Rolwes cannot meet this burden because of her pre-existing conditions and risk factors that cannot scientifically be linked to Remicade® (See Defendants' Daubert Motion to Exclude Dr. Marks to be filed on March 1, 2004). In other words, there exist equally probable causes of Ms. Rolwes' tuberculosis reactivation, such that it is not more likely that Remicade® caused the reactivation than any or all of the other factors. Thus, Centocor is entitled to summary judgment. See, e.g., Nelson, 92 F. Supp. 2d at 973 (granting summary judgment due to lack of admissible evidence on causation).

1. Ms. Rolwes' Had Multiple Pre-Existing Conditions and Risk Factors

Ms. Rolwes experienced health problems and was prescribed numerous medications years prior to her use of Remicade® that put her at risk for her tuberculosis to "activate." One, just having latent tuberculosis put Ms. Rolwes at an increased risk of developing active tuberculosis infection. (Uncontroverted Facts ¶¶ 1, 16.) Two, Ms. Rolwes was diagnosed with rheumatoid arthritis in the early 1980s, a condition that is known to suppress the immune system and lead to infections including tuberculosis. (Id. ¶¶ 4, 14, 56.) Three, several drugs that Ms. Rolwes was taking for her rheumatoid arthritis prior to her Remicade® therapy are immunocompromising and independently increased her risk of tuberculosis. (Id. ¶¶ 9, 56-57, 59-60.) Four, Ms. Rolwes' increasing age made her more susceptible to activation of her latent tuberculosis. (Id. ¶¶ 56-57, 60.) Five, Ms. Rolwes had a hysterectomy soon after beginning her Remicade® therapy, a procedure which also put her at risk of infection. (Id. ¶ 58.)

There is no scientifically demonstrated connection between Remicade® and any of these other risk factors, and Ms. Rolwes' inability to scientifically rule out any of these factors shows that Remicade® is at most one of many equally probable causes of her tuberculosis. (See, e.g., id. ¶¶ 56-57, 59-60.) Moreover, the evidence concerning the alleged temporal relationship

and type of tuberculosis Ms. Rolwes developed (limited pulmonary), makes it less likely that Remicade® caused the activation of Ms. Rolwes' tuberculosis. (See id. ¶ 63.)

Because these other independent risks cannot be reasonably excluded as a cause Ms. Rolwes' infection, summary judgment should be granted. See Conde v. Velsicol Chem. Corp., 24 F.3d 809, 813-14 (6th Cir. 1994) (expert's inability to exclude other possible causes of the plaintiff's injuries is failure to prove causation); Sorensen v. Shaklee Corp., 31 F.3d 638, 649 (8th Cir. 1994) (same); Wheat v. Pfizer, Inc., 31 F.3d 340, 342-43 (5th Cir. 1991) (same); Nelson, 92 F. Supp. 2d at 973 (granting summary judgment due to lack of admissible evidence on causation); Wade-Greaux v. Whitehall Laboratories, 874 F. Supp. 1441, 1478 (D.V.I.), aff'd, 46 F.3d 1120 (3d Cir. 1994) (same).

Ms. Rolwes' treating physician, her husband, and even Ms. Rolwes noticed an improvement in her condition after she started Remicade®. For example, Ms. Rolwes' painful nodules that interfered with her ability to function disappeared after she started using Remicade.® (Uncontroverted Facts ¶ 41-42, 44.) Indeed, Ms. Rolwes' own expert concedes that Remicade® improved her rheumatoid arthritis symptoms and was having a positive effect. (Id. ¶ 43.)

As the record clearly shows, Ms. Rolwes was benefiting from Remicade® and her rheumatoid arthritis symptoms were improving. There is no evidence indicating that Remicade® "more likely than not" caused the reactivation of her latent tuberculosis and Dr. Marks' "net opinion" that Remicade® caused the activation of Ms. Rolwes' latent tuberculosis because he believes it cannot be disputed (see id. ¶ 50), is not a sufficient basis to deny Centocor's motion. See Weisgram v. Marley Co. 169 F.3d 514, 519 (8th Cir. 1999) (expert may not provide speculative testimony), aff'd, 528 U.S. 440 (2000); Target Mkt. Publ'g, Inc. v. Advo, Inc., 136 F.3d 1139, 1143 (7th Cir. 1998) (speculative expert testimony excluded); Rosen v. Ciba-Geigy Corp., 78 F.3d 316, 318 (7th Cir. 1996) (expert evidence most be "genuinely scientific, as

distinct from being unscientific speculation offered by a genuine scientist"); Greensboro Prof'l Firefighters Ass'n v. City of Greensboro, 64 F.3d 962, 967 (4th Cir. 1995) (excluding speculative testimony of "expert"); Claar v. Burlington N. R.R. Co., 29 F.3d 499, 502-03 (9th Cir. 1994) (rejecting expert conclusions that are based on "subjective belief and unsupported speculation").

POINT II

CENTOCOR ADEQUATELY WARNED MS. ROLWES' TREATING PHYSICIAN

Even if this Court finds that Ms. Rolwes can make out a prima facie showing of medical causation, Centocor cannot be held liable because it provided Ms. Rolwes' prescribing physician, Dr. Uchiyama, with adequate warnings about Remicade®.

Missouri follows the "learned intermediary" doctrine. Kirsch v. Picker Int'l, Inc., 753 F.2d 670, 671 (8th Cir. 1985); Doe v. Alpha Therapeutic Corp., 3 S.W.3d 404, 419-20 (Mo. Ct. App. 1999). In cases involving prescription products, a manufacturer need only provide warnings to the treating physician and has no duty to inform the individual of the medicine's potential side effects. Kirsch, 753 F.2d at 671. As a "learned intermediary" between the manufacturer and the consumer, the prescribing physician balances risks and benefits and provides appropriate warnings and instructions to patients. Id.; see also Donahue v. Phillips Petroleum Co., 866 F.2d 1008, 1013 n.9 (8th Cir. 1989) ("The rationale [behind the learned intermediary doctrine is] that a patient may obtain the [prescribed drug] only through a qualified professional who presumably will explain the dangers of the [drug] to the patient . . . ."). Thus, "a warning to the doctor is deemed a warning to the patient; the manufacturer need not communicate directly with all ultimate users of prescription drugs." Kirsch, 753 F.2d at 671. A manufacturer is not liable for a patient's medicine-related injuries when it provides warnings to the treating physician.

Here, Dr. Uchiyama was aware of the increased risk of infections, including tuberculosis, associated with Remicade® at the time he prescribed the medicine to Ms. Rolwes. (Uncontroverted Facts ¶ 35.) Based on his knowledge of Remicade®'s potential risks, Dr. Uchiyama exercised his clinical judgment in prescribing it to Ms. Rolwes to alleviate the symptoms of her rheumatoid arthritis. (Id. ¶¶ 13-15, 28, 35-36.) Dr. Uchiyama treated Ms. Rolwes with knowledge of the benefits and risks of Remicade®. (Id.)

Centocor provided adequate warnings and updated the prescribing information for Remicade® when appropriate. (Id. ¶¶ 29, 69-75.) These warnings, which Ms. Rolwes' expert says are "very helpful," describe the risk that Ms. Rolwes alleges she experienced. (Id. ¶ 76.) And courts consistently have held that when a manufacturer's warnings discuss the injury alleged by the plaintiff, summary judgment should be granted. See Ziliak v. AstraZeneca LP, 324 F.3d 518, 521 (7th Cir. 2003); Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 266-68 (5th Cir. 2002); Adams v. Synthes Spine Co., 298 F.3d 1114, 1118-19 (9th Cir. 2001).

Here, the facts are that Centocor: (1) included a "red flag" warning in November 1999 about tuberculosis when only two reports out of almost 200,000 people receiving Remicade® had been reported; and (ii) updated this warning with "very helpful" information after Centocor received additional reports that independent experts found inconclusive. Moreover, all of Centocor's warnings and the underlying data were reviewed and approved by FDA.

When FDA issues an "approval" letter for a medicine, it represents the agency's official conclusion that the benefits of the drug outweigh any risks. See 21 U.S.C. § 355; 21 C.F.R. § 201.56-57. This regulatory conclusion is the product of an extensive and detailed review of all the available safety and efficacy studies. See, e.g., Grundberg, 813 P.2d at 98. Six times since August 1998, FDA recognized and reaffirmed that adequate information has been

presented to demonstrate that Remicade® is safe and effective for use as recommended in the medicine's approved Indication. (Uncontroverted Facts ¶ 68.) While not dispositive, this evidence strongly supports Centocor's position that its warnings are adequate. See Pipitone v. Biomatrix, Inc., 228 F3d 239, 250 (5th Cir. 2002); A.L. Pharma, Inc. v. Shalala, 62 F.3d 1484, 1490 (D.C. Cir. 1995) (courts defer to FDA evaluations of scientific data); Hurley v. Lederle Labs., 863 F.2d 1173, 1179 (5th Cir. 1988) (FDA approval of biologic warnings dispositive.)

Courts repeatedly have cautioned against permitting a plaintiff or her expert to second-guess FDA determinations. See Ziliak, 324 F.3d at 520-21 (specifically rejecting Dr. Marks' "net" opinion that contradicted FDA-approved warnings); Thomas v. Hoffmann-LaRoche Inc., 949 F.2d 806 (5th Cir.), cert. denied, 504 U.S. 956 (1992); Hackett v. G.D. Searle & Co., 246 F. Supp. 2d 591, 595 (W.D. Tex. 2002) (expressing concern that allowing plaintiffs to second-guess FDA would create disincentive to companies to develop new medicines); See also Touchet v. Ace Med., Co., No. CIV. A. 96-3534 1998 WL 531887, at *5 (E.D. La. Aug. 24, 1998); Jacobs v. Dista Prods. Co., 693 F. Supp. 1029, 1035 (D. Wyo. 1988).

POINT III

MS. ROLWES CANNOT ESTABLISH THAT CENTOCOR'S WARNINGS PROXIMATELY CAUSED HER INJURY

Centocor also is entitled to summary judgment because Ms. Rolwes cannot sustain her burden of proving that any alleged wrongdoing by Centocor proximately caused injury to her.

To establish proximate cause, Ms. Rolwes must show that the alleged injury was a "natural and probable consequence" of Centocor's actions. DiCarlo v. Keller Ladders, Inc., 211 F.3d 465, 467 (8th Cir. 2000). In the context of prescription products, "[t]he plaintiff has the burden of showing that the absence of a warning caused the injury." Kirsch, 753 F.2d at 671. In

other words, if the injury would have occurred regardless of the adequacy of the warning, it cannot be considered a "natural and probable consequence." The "learned intermediary" doctrine provides that the alleged failure of a pharmaceutical manufacturer to give a physician an adequate warning is not the proximate cause of an injury if the prescribing physician already had independent knowledge of an alleged risk. Id.

A. Ms. Rolwes Cannot Establish that Dr. Uchiyama Possessed Inadequate Information Concerning the Risks of a Tuberculosis Infection

Dr. Uchiyama had independent information about the risk of infection with Remicade® and how to treat patients with latent tuberculosis. Thus, Ms. Rolwes cannot demonstrate proximate cause and Centocor is entitled to summary judgment. See, e.g., Anderson v. F.J. Little Machine Co., 68 F.3d 1113, 1115 (8th Cir. 1995); Kirsch, 753 F.2d at 671.

Dr. Uchiyama is on record stating:

- He independently knew how to use immunocompromising medicines;
- He independently knew how to treat patients at risk for infection with immunocompromising medicine;
- He knew Remicade® was an immunocompromising medicine; and
- He knew Remicade® carried with it an increased risk of serious and fatal infections, including tuberculosis.

(Uncontroverted Facts ¶¶ 13-16, 35-36.) Moreover, Dr. Marks agrees that rheumatologists are taught these principles in their residency training (Id. ¶¶ 14-15.) In addition, the uncontroverted proof demonstrates that Dr. Uchiyama understood the benefits of prescribing Remicade® to Ms. Rolwes and felt that those benefits outweighed the potential risks. (Id. ¶¶ 13-15, 28, 35-36.)

Centocor cannot be held liable because Ms. Rolwes' physician was independently aware of a risk and made an informed, reasoned, clinical judgment to treat Ms. Rolwes with Remicade®. Accordingly, Ms. Rolwes cannot establish that an alleged "failure to warn"

proximately caused her any injury. Kirsch, 753 F.2d at 671 (finding failure to warn not proximate cause of injury where doctor was already familiar with risks of treatment).

B. Ms. Rolwes Cannot Demonstrate a Causal Connection Between Centocor's Warnings and Dr. Uchiyama's Decision to Treat Her with Remicade®

To establish proximate cause, Ms. Rolwes must introduce facts not only to show that Dr. Uchiyama lacked knowledge about the potential risks associated with Remicade®, but also must show that adequate warnings would have prevented her injury. Stated differently, Ms. Rolwes must prove that had Centocor given different warnings, Dr. Uchiyama would not have prescribed or continued Ms. Rolwes on Remicade®. See, e.g., Anderson, 68 F.3d at 1115 ("This evidence of knowledge negates the causation element [plaintiffs] must prove, since a warning would not have provided additional information that would have influenced [plaintiff's] conduct.").

The facts show that Dr. Uchiyama was fully informed of the benefits and risks of prescribing Remicade® . (Uncontroverted Facts ¶¶ 13-15, 23-25, 28-29, 35.) Ms. Rolwes cannot prove that the warnings provided were inadequate or that alternative warnings would have influenced Dr. Uchiyama to treat Ms. Rolwes any differently. This lack of proof compels the conclusion that there is no causal connection between Centocor's warnings and any injury to Ms. Rolwes, and therefore no showing of proximate cause.

C. Ms. Rolwes Ignored A "Red Flag"

Ms. Rolwes admits that if she carefully read the package insert Dr. Uchiyama gave her in January 2000, she would not have agreed to start Remicade® therapy.

That Dr. Uchiyama gave Ms. Rolwes the package insert cannot be disputed because: (a) Dr. Uchiyama swears that he did; and (b) Ms. Rolwes destroyed or lost the materials Dr. Uchiyama gave her after this litigation was commenced. (Id. ¶¶ 23, 27.) Thus, an adverse inference regarding the content of the materials provided to Ms. Rolwes must be drawn.

See Evans v. Robbins, 897 F.2d 966, 970 (8th Cir. 1990) ("[A] negative inference arises from a [party's] failure to produce documents shown to have been in his possession. The inference is that the documents would have been damaging to the [party].").

When a plaintiff fails to read or heed a "red flag," she cannot avoid dismissal of her case. See Anderson, 68 F.3d at 1115 (affirming grant of summary judgment where plaintiff had knowledge of danger and additional information would not have influenced conduct).

POINT IV

NO BASIS EXISTS FOR ANY CLAIM AGAINST CENTOCOR'S PARENT, JOHNSON & JOHNSON

A parent corporation generally is not liable for the acts of its subsidiaries. The mere existence of a parent-subsidiary relationship does not impose liability on the parent absent misuse of the corporate form for improper purposes. See United States v. Bestfoods, 524 U.S. 51, 61-62 (1998). Ms. Rolwes has no evidence showing any substantial direct participation by Johnson & Johnson in any conduct that allegedly caused her injury. To the contrary, Johnson & Johnson did not research, develop, market, or manufacture Remicade® itself or employ anyone to do so on its behalf. (Uncontroverted Facts ¶ 81.) In addition, Johnson & Johnson and Centocor manage and operate their own day-to-day business activities independently of each other, maintaining separate legal identities. (Id. ¶ 82.) Moreover, Ms. Rolwes' expert cannot offer any legal basis upon which liability could be imposed on Johnson & Johnson for Ms. Rolwes' injuries. Finally, Ms. Rolwes cannot show that Johnson & Johnson dominated Centocor to the extent that the parent/subsidiary relationship should be disregarded. See Bestfoods, 524 U.S. at 61-73. Were this Court to hold otherwise, the corporate form would become meaningless.

CONCLUSION

For the reasons set forth above, Centocor and Johnson & Johnson respectfully request that their motion for summary judgment be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

The undersigned certifies that a copy of the foregoing document was filed with the Court's electronic filing system and served on the following counsel of record by means of the Court's Notice of Electronic Filing, on this 17th day of February, 2004.

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